REMARKS

Amendment summary

The recited concentrations of phosphatidylserine in the first and third reagents in Claims 8 and are amended. Support for these amendments is found, e.g., in the paragraph bridging pages 7 and 8 of the present specification.

Claims 8 and 21 are further amended to recite that the concentration of the phosphatidylserine in the first reagent is higher than that of the phosphatidylserine in the third reagent. Support for this amendment is found, e.g., on page 8, lines 13-15 of the present specification.

Claim 21 is further amended to recite that the content of phosphatidylserine to the total content of the phospholipids in the first reagent is different from the content of phosphatidylserine to the total content of the phospholipids in the third reagent. Support for this amendment is found, e.g., in the third full paragraph on page 5 of the present specification.

Upon entry of this Amendment, claims 6-21 and 24-27 will be pending.

No new matter is added by this Amendment, and Applicant respectfully submits that entry of this Amendment is proper.

Status of the claims

Claims 6-8, 19-21, and 25-27 were rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. Claims 6 and 8-12 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moore et al. (EP 566,333) (hereinafter "Moore") in light of Webster's Dictionary. In addition, claims 13, 21, 24, and 27 were rejected

under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moore in light of Webster's Dictionary in view of Smirnov et al. Claims 14-20 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moore in light of Webster's Dictionary in view of Rosen et al. (U.S. Patent No. 6,395,501) (hereinafter "Rosen"). Further, claims 7, 13, 21, and 24-27 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moore in light of Webster's Dictionary in view of Smirnov et al., further in view of Rosen. Finally, claims 6-21 and 24-27 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over co-pending U.S. Application No. 11/050,766.

Response to rejection under 35 U.S.C. § 112

Claims 6-8, 19-21, and 25-27 were rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. Applicant respectfully disagrees that the claims presented new matter.

However, in order to advance prosecution, Applicant notes that the present claims have been amended. Accordingly, Applicant respectfully submits that the present claims do not contain new matter, and respectfully requests the reconsideration and withdrawal of this § 112 rejection.

Addressing Brown and Smirnoff

On page 3 of the Office Action, Examiner asserts that she may reconsider the previous rejections of the claims based on Brown (U.S. Patent No. 5,314,695) and Smirnov et al.

Applicant respectfully submits that neither of Brown nor Smirnov et al. discloses a reagent kit prepared by combining two reagents, each of which has a specific PS concentration, as recited in the present claims. Specifically, in the two reagents used in the kit of the present invention, have different contents of PS to the total content of the phospholipids (hereinafter, the "PS content ratio"). Furthermore, neither Brown nor Smirnov et al. teach or suggest that lupus anticoagulant (LA) can be detected by measuring coagulation times using a specific combination of two reagents, each having specific PS concentration and having different PS content ratios.

Accordingly, Applicant respectfully submits that independent claims 8 and 21, and their dependent claims, are not anticipated by Brown or Smirnov et al. in light of Webster' s Dictionary.

Response to rejection of claims 6 and 8-12 under 35 U.S.C. § 102(b) based on Moore in light of Webster's Dictionary

Claims 6 and 8-12 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moore in light of Webster's Dictionary. Applicant respectfully submits that Moore does not anticipate the present claims.

Independent claim 8 recites a reagent kit for detecting lupus anticoagulant in blood comprising a first reagent containing phospholipids including phosphatidylserine, the concentration of the phosphatidylserine in the first reagent ranging from 3 μg/ml to 1000 μg/ml; a second reagent containing calcium ions; a third reagent containing phospholipids including phosphatidylserine, the concentration of the phosphatidylserine in the third reagent ranging from 0.2 μg/ml to 200 μg/ml; and a fourth reagent containing calcium ions In addition, the content of phosphatidylserine to the total content of the phospholipids in the first reagent is different from

the content of phosphatidylserine to the total content of the phospholipids in the third reagent, and the concentration of the phosphatidylserine in the first reagent is higher than that of the phosphatidylserine in the third reagent. The lupus anticoagulant is detected based on a first coagulation time obtained by using the first and second reagents, and a second coagulation time obtained by using the third and fourth reagents.

Conversely, Moore discloses activated partial thromboplastin time (APTT) reagent and prothrombin time (PT) reagent containing synthetic phospholipids. Moore discloses seventeen PL reagents comprising varying amounts of PS, phosphatidylethanolamine (PE) and pohosphatidylcholine (PC) in Table II. Table II also depicts clotting times for various samples measured using the 17 PL reagents.

Applicant respectfully submits that Moore does not disclose the following features of the present invention:

a) preparing a reagent kit by combining two reagents, each of which has a specific PS concentration, with the PS concentrations in being different from each other;

b) a PS content ratio in the first reagent that is different from a PS content ratio in the third reagent (where PS content ratio = (PS content) / (PL content)); and

c) LA detection based on a first coagulation time obtained by using the first and second reagents, and a second coagulation time obtained by using the third and fourth reagents.

The reagent kit of the present invention is the combination of two reagents having the above features (a) and (b), and excludes a combination of one reagent and its diluted reagent, because the combination of one PL reagent (e.g. RVVT) and its diluted reagent (d-RVVT) is not sufficient to discriminate LA-positive plasma from abnormal blood plasma, such as samples of

blood administered with warfarin or heparin. As shown in Table 3 of page 17 of the present specification, not only LA-positive plasma samples treated with the d-RVVT reagent, but also other abnormal blood samples treated with the same showed longer coagulation times than samples treated with the RVVT reagent.

On the other hand, when a reagent combination having the above feature (b) is used, such as a combination of H-APTT and L-APTT, shown in the Examples of the present specification, LA-positive plasma samples treated with L-APTT reagent have longer coagulation times than ones treated with the H-APTT reagent, while other abnormal samples treated with the L-APTT reagent have similar coagulation times to ones treated with the H-APTT reagent (see Table 2 and pages 15 and 16 of the present specification).

This advantage of the reagent kit of the present invention is not taught or suggested by Moore. Accordingly, because Moore does not teach that the above feature (b) contributes to the discrimination of LA-positive samples from other abnormal samples, Applicant respectfully submits that Moore does not anticipate the present claims.

Therefore, Applicant respectfully requests the reconsideration and withdrawal of this § 102 rejection.

Response to rejection of claims 13, 21, 24, and 27 under 35 U.S.C. § 103(a) based on Moore in light of Webster's Dictionary in view of Smirnov et al.

Claims 13, 21, 24, and 27 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moore in light of Webster's Dictionary in view of Smirnov et al. Applicant respectfully submits that the combination of these references does not render obvious the presently claimed invention.

Applicant first respectfully submits that these cited references do not render obvious the presently claimed invention because, as noted above, Moore does not disclose the above-mentioned features (a) to (c) of the present invention, and Smirnov et al. does not, either. Nor do these references teach that a reagent kit having feature (b) advantageously discriminates an LA-positive sample from other abnormal samples.

With specific reference to claim 13, which recites that the concentration of the phosphatidylethanolamine in each of the first and third reagents ranges from 1 μg/ml to 30 μg/ml, and the concentration of the phosphatidylcholine in each of the first and third reagents ranges from 20 μg/ml to 100 μg/ml, Applicant respectfully submits that neither Moore nor Smirnov et al., alone or in combination, renders obvious this aspect of the present invention.

As previously noted, Moore discloses 17 formulations, each having a different PL, in Table II. However, there are no reagent combinations disclosed within Moore which fall within the scope of present claim 13. Applicant notes that the Office Action sets forth the position that it would have been obvious to make PL preparations having PS: 11.0 μg/ml, PE: 27.0 μg/ml, PC: 72.5 μg/m1 (modified Run 15); and PS: 75.0 μg/ml; PE: 27.0μg/ml and PC: 72.5 μg/ml (modified Run 2) (see page 7 of the Office Action). In addition, Applicant notes that the Office Action also set forth the position that the ordinary artisan would have been motivated to do so because both Moore and Smirnov teach that procoagulant and anticoagulant reactions are highly sensitive to PL content of the reagent used to measure the same (see page 7 of the Office Action). Applicant respectfully disagrees.

Both Moore and Smirnov fail to teach that the combination having the above feature (b) is a combination capable of discriminating an LA-positive sample from other abnormal samples.

As previously discussed, to obtain a regent kit capable of discriminating LA-positive samples from other abnormal samples, two kinds of reagents should be used, each having a specific PS, PE, and PC concentration, as well as having a PS content ratio that is different from the other's PS content ratio.

Accordingly, Applicant respectfully submits that the reagent kit of claim 13, which has significant advantage of discriminating LA-positive sample from other abnormal samples, is not obvious in view of the combined teachings of Moore and Smirnov et al.

In view of the above, Applicant respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Response to rejections citing Rosen

Claims 14-20 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moore in light of Webster's Dictionary in view of Rosen. Further, claims 7, 13, 21, and 24-27 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moore in light of Webster's Dictionary in view of Smirnov et al., further in view of Rosen.

Applicant respectfully submits that Rosen does not remedy the deficiencies of either Moore or Smirnov et al., and that therefore these combinations of references do not render obvious the presently claimed invention.

Rosen discloses that phospholipoids in combination with Russell' s venom, ellagic acid, kaolin or silica derivatives are well-known activators of the coagulation pathway and are suitable for measuring anticoagulant activity. In addition, Rosen teaches that the activator is added to the PL reagent.

However, Rosen does not disclose the above features (a) to (c) of the present invention. Specifically, Rosen does not teach that feature (b) advantageously discriminates an LA-positive sample from other abnormal blood samples.

Accordingly, Applicant respectfully submits that the cited references do not render obvious the presently claimed invention. Applicant therefore respectfully requests the reconsideration and withdrawal of this rejection.

Response to provisional obviousness-type double patenting rejection

Claims 6-21 and 24-27 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over co-pending U.S. Application No. 11/050,766. Applicant files herewith a Terminal Disclaimer, obviating this rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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